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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/764,056

Applicant(s)

GAUE ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-20 is/are pending in the application.  
4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-9 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 23 January 2004.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of claims 1-9, cancellation of claim 10 without prejudice and withdrawal of claims 11-20 as being directed to a non-elected invention, in the reply filed on 13 July 2005 is acknowledged.

Claims 1-9 are under examination.

### ***Specification Objections***

2. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, page 26 of the specification. Applicant must

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submit a CRF copy and paper copy of the Sequence Listing, a statement that the content of the paper and computer readable copies are the same and where applicable include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(d), as well as an amendment directing its entry into the specification.

Failure to comply with these requirements in response to this Office Action will be considered non-responsive to this Office Action.

Page 15, line 1 of paragraph 0065 of the specification is objected to because of the word "plasm". This term is not recognized in the art and the meaning of this word is unclear.

### ***Priority***

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 26 July 2001. It is noted, however, that applicant has not filed a certified copy of the 101 36 378.8 application as required by 35 U.S.C. 119(b). In addition, Applicant has not provided a translation of the 101 36 378.8 application. 35 U.S.C. 365 (c) states:

"If any claim for the benefit of an earlier filing date is based on a prior international application which designated but did not originate in the United States, the Director may require the filing in the Patent and Trademark Office of a certified copy of such application together with a translation thereof into the English language, if it was filed in another language."

See also 35 U.S.C. 375 (b) where it states:

"Where due to an incorrect translation the scope of a patent granted on an international application designating the United States, which was not originally filed in the English language, exceeds the scope of the international application in its original language, a court of competent jurisdiction may retroactively limit the scope of the patent, by declaring it unenforceable to the extent that it exceeds the scope of the international application in its original language".

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(Added Nov. 14, 1975, Public Law 94-131, sec. 1, 89 Stat. 689; amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-582 (S. 1948 sec. 4732(a)(10)(A)).)

***Claim Rejections - 35 USC § 112, first paragraph***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of completely male sterile plants of *Lolium perenne* comprising mutagenizing caryopses material of *L. perenne* with the mutagenic agent N-ethyl urea ( $C_3H_8N_2O$ ) in a concentration of 0.025% for 18 hours, does not reasonably provide enablement for a method for producing completely male sterile plants of any plant of the genus *Lolium* comprising mutagenizing caryopses material of any plant, with any mutagenic agent, of the genus *Lolium*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,

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the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The claims are broadly drawn to a method for producing completely male sterile plants of any plant of the genus *Lolium* comprising mutagenizing caryopses material of any plant, with any mutagenic agent, of the genus *Lolium* and identifying at least one completely male sterile *Lolium* plant.

The specification only discloses the production of completely male sterile plants of *Lolium perenne* comprising mutagenizing caryopses material of *L. perenne* with the mutagenic agent N-ethyl urea ( $C_3H_8N_2O$ ) in a concentration of 0.025% for 18 hours (see page 14, paragraph 0060).

The specification states, "By repeated back-crossing, the transfer of the MSL plasm from *L. perenne* to *L. multiflorum* could be achieved" (see page 15, paragraph 0065); however, the specification fails to provide any evidence of any *L. multiflorum* plants that are completely male sterile or used in the claimed method nor is there any evidence of any *L. hybridum* plants that are completely male sterile or used in the claimed method as is claimed in claim 6. Furthermore, the specification does not provide any evidence of male sterile plants from the broad genus of *Lolium* plants.

The specification only provides evidence of *L. perenne* plants having complete male sterility and only provides evidence of *L. perenne* plants used in the claimed method (see page 14, paragraph 0060; page 16, paragraph 0073 and page 24, Table 3).

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The use of mutagenizing chemicals to induce particular traits is unpredictable. Poehlman et al (Breeding Field Crops, fourth edition, 1995, Chapter 6, Mutation pages 108-109) teach that it is not possible to direct the mutation process so that a specific type of mutation can be produced using chemical mutagens (see page 109, third paragraph).

Given the lack of guidance regarding the broad genus of *Lolium* plants, the absence of working examples for the broad genus of *Lolium* plants and the unpredictability of using mutagenizing chemicals to induce particular traits, it would require undue trial and error experimentation to use the claimed invention.

***Claim Rejections - 35 USC § 112, second paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step appears to be a regeneration step after the mutagenizing of caryopses material. It does not appear possible to go from mutagenizing caryopses material directly to the identification of a completely male sterile *Loium* plant without first regenerating the mutagenic material into plantlets or plants.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. The term "the method according to Alexander" does not particularly point out the exact method nor does it distinguish it from other methods that may used by Alexander.

### ***Conclusion***

8. Claims 1-9 are free of the prior art given the failure of the prior art to teach or suggest a method for producing completely male sterile plants of the genus *Lolium* comprising mutagenizing caryopses material of wild-type plants of said genus.

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

August 29, 2005

**DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read "David H. Kruse". The signature is fluid and cursive, with the first name "David" being more prominent and the last name "Kruse" following in a similar style.